K 100756

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company: ..... 3M ESPE AG

Street: ..... ESPE Platz

ZIP-Code, City: ..... D-82229 Seefeld

Federal State: ..... Bavaria

Country: ..... Germany

Establishment Registration Number 9611385

Official Correspondent: ..... Dr. Desi W. Soegiarto,

..... Regulatory Affairs Specialist

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Date: ..... May 18, 2010

JUN -2 2010

Name of Device

Proprietary Name: ..... Malta

Classification Name: ..... Dental cement other than zinc oxide-eugenol

Common Name: ..... Self adhesive cement

Predicate Devices

Unicem by 3M ESPE, Germany K020256, K094007

Panavia F 2.0 by Kuraray Medical Inc., Japan K032455

Maxcem 2 by Kerr Corporation, U.S.A.,
presumably marketed as Maxcem Elite K073209

Description for the Premarket Notification

Malta is classified as a Dental cement other than zinc oxide-eugenol (21 C.F.R. §872.3275 [b]) because it is a device composed of various materials other than zinc oxide-eugenol.

Malta is a dual-curing, self-adhesive resin cement available in an automix syringe. It contains bi-functional (meth)acrylate. The proportion of inorganic fillers is about 70 % by weight; the grain size (D 90 %) is about 12.5 µm. The mixing ratio, based on volume, is 1 part base paste : 1 part catalyst paste. The two pastes are mixed by a static single use mixer attached to the syringe. Malta is available in various shades.

Predicate devices to which Malta has been compared are Unicem by 3M ESPE, Germany (K020256, K094007), Panavia F 2.0 by Kuraray Medical Inc., Japan (K032455) and Maxcem 2 by Kerr Corporation, U.S.A., presumably marketed as Maxcem Elite (K073209).

As its predicate devices, Malta is a dual-curing, resin-based cement. Like Maxcem Elite, Malta is a paste/paste product offered in an automix delivery system.

The intended use of Malta is comparable to the area of the intended use of the predicate devices of Malta.

In this 510(k) premarket notification Malta has been compared to its predicate devices with regard to chemical composition, performance data and indications for use. The comparison for chemistry, performance data and indications for use shows that Malta is substantially equivalent to the predicate devices: Unicem by 3M ESPE, Germany (K020256, K094007), Panavia F 2.0 by Kuraray Medical Inc., Japan (K032455) and Maxcem 2 by Kerr Corporation, U.S.A., presumably marketed as Maxcem Elite (K073209).

The following table shows the performance data of Malta and its predicate device Unicem:

				Malta	Unicem
		Method	Limit	Results	
Film thickness		ISO 4049:2000	< 50 µm	13 ± 1	12 ± 2
Setting time		ISO 4049:2000	< 10 min	03:30	05:00
Radiopacity		ISO 4049:2000	> 1.0 mm	1.8	2.4
Flexural strength	dark cured	ISO 4049:2000	> 50 MPa	84 ± 12	53 ± 7
	light cured		> 50 MPa	111 ± 16	64 ± 6
Compressive strength	dark cured	ISO 9917:2001	na [MPa]	263 ± 9	209 ± 15
	light cured		na [MPa]	256 ± 36	218 ± 13
Surface hardness	dark cured	ISO 2039-1:2000	na [MPa]	190 ± 20	209 ± 13
	light cured		na [MPa]	212 ± 30	151 ± 10

Biocompatibility testing was carried out.

In summary, it can be concluded that Malta is as safe and effective as the predicate devices: Unicem by 3M ESPE, Germany (K020256, K094007), Panavia F 2.0 by Kuraray Medical Inc., Japan (K032455) and Maxcem 2 by Kerr Corporation, U.S.A., presumably marketed as Maxcem Elite (K073209).

Indications for Use:

Final cementing of all-ceramic, composite, or metal inlays, onlays, crowns and bridges;

2-3-unit Maryland bridges and 3-unit inlay/onlay bridges (excluded for patients with bruxism or periodontitis);

Final cementing of posts and screws;

Final cementation of all-ceramic, composite, or metal restorations on implant abutments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dr. Desi Soegiarto
Regulatory Affairs Specialist
3M ESPE AG Dental Products
ESPE Platz
Seefeld, Bavaria
Germany D-82229

JUN - 2 2010

Re: K100756
Trade/Device Name: Malta
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: March 12, 2010
Received: March 17, 2010

Dear Dr. Soegiarto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 100756

Device Name: Malta

Indications For Use: Final cementing of all-ceramic, composite, or metal inlays, onlays, crowns and bridges; 2-3-unit Maryland bridges and 3-unit inlay/onlay bridges (excluded for patients with bruxism or periodontitis);
Final cementing of posts and screws;
Final cementation of all-ceramic, composite, or metal restorations on implant abutments.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K.Beltz DDS for Dr. K.P. Mulray
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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